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No. 2014-1773

In the United States Court of Appeals for the Federal Circuit

IN RE RONALD S. KARPF

ON APPEAL FROM THE
UNITED STATES PATENT AND TRADEMARK OFFICE
PATENT TRIAL AND APPEAL BOARD
APPEAL 2011-007657 (APPLICATION 11/074,053)

BRIEF OF APPELLANT RONALD S. KARPF

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CERTIFICATE OF INTEREST

Pursuant to Federal Circuit Rule 47.4, undersigned counsel for Appellant Ronald S. Karpf certifies the following:

- 1. The full name of every party or amicus represented by me is: Ronald S. Karpf.
- The name of the real party in interest (if the party named in the 2. caption is not the real party in interest) represented by me is: Electronic Compliance Promoter, Inc.
- All parent corporations and any publicly held companies that own 10 3. percent or more of the stock of the party or amicus curiae represented by me are: None.
- The names of all law firms and partners or associates that appeared for 4. the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are: Adam L. Perlman and Andrew V. Trask of Williams & Connolly LLP; Christian J. Hurt of Nix Patterson & Roach, LLP; and Eric Oliver of Dickstein Shapiro LLP.

January 9, 2015 /s/ Andrew V. Trask

ANDREW V. TRASK

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STATEMENT OF RELATED CASES

Counsel for Appellant is unaware of any other appeal in connection with the Patent Trial and Appeal Board ("Board") proceeding below before this or any other Court. Counsel for Appellant is also unaware of any other case pending in this or any other Court that will directly affect, or be directly affected by, the Court's decision in this appeal.

This Court decided a prior appeal from the Board involving a related patent application with the same specification but different claims. *See In re Karpf*, 576 F. App'x 968 (Fed. Cir. 2014) (O'Malley, Reyna, and Hughes, JJ.).

JURISDICTIONAL STATEMENT

This is an appeal from a final decision of the Board. This Court has jurisdiction under 28 U.S.C. § 1295(a)(4)(A).

STATEMENT OF THE ISSUES

Appellant seeks reversal of the Board's decision rejecting claims 26 through 37 of U.S. Patent Application 11/074,053 (the "'053 application"). The appeal presents the following three issues:

(1) whether substantial evidence supports the Board's findings that U.S. Patent No. 7,593,952 ("Soll") anticipates claims 26–34, 36, and 37 of the '053 application;

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(2) whether the Board legally erred in concluding that Soll renders obvious claim 35 of the '053 application; and

(3) whether the Board legally erred in concluding that claim 28 is not patenteligible under 35 U.S.C. § 101.

STATEMENT OF THE CASE

This appeal challenges the Board's decision on December 12, 2013 (J.A. 1–16) rejecting claims 26 through 37 of the '053 application, as well as the Board's decision denying rehearing on May 20, 2014 (J.A. 17–26).

STATEMENT OF THE FACTS

A. The '053 Patent Application and the Pending Claims

The invention at issue relates to an electronic medical records system for promoting patients' compliance with their doctors' treatment instructions. The inventors, Ronald S. Karpf and Arthur B. White, filed the '053 application in 2005.¹ The '053 application claims priority to a patent application filed on August 12, 1999, which Dr. Karpf drafted and filed *pro se*. See J.A. 173, 588–89.

In the course of his work in the field of diabetes mellitus, Dr. Karpf observed a significant problem with "compliance," i.e., patients' failure to follow their doctors' "post-examination treatment instructions." J.A. 30. As the '053

Dr. White passed away during the proceedings below. For simplicity, this Brief refers to the inventors as "Dr. Karpf."

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application explains, poor compliance often stems from a patient leaving the doctor's office "without a clear understanding of the diagnosis or recommended course of action." J.A. 31. Patients, moreover, are "often unable to focus on the instructions for treatment," have "difficulty understanding the medical terminology," and have "cognitive difficulty in remembering instructions for complicated regimens." J.A. 31–32. Poor patient compliance "is a real problem with serious medical consequences." J.A. 32.

When Dr. Karpf filed his patent application, there was a long-standing need to improve patients' compliance with their doctor's instructions. As of 1999, the primary means for improving patient compliance entailed providing patients with "pamphlets and/or packets of printed information appropriate to the patient's complaint," which were "used to supplement the practitioner's verbal instructions." J.A. 32. A patient experiencing lower back pain, for example, could receive from the doctor "a booklet describing the problem and the appropriate exercise treatments." *Id*.

The '053 application explains that although the use of such printed materials has benefits, it also "has serious problems." *Id.* Such problems include the difficulty of stocking printed materials for a large number of illnesses and in a variety of languages, and the fact that "more recent medical advances and treatment guidelines may easily outdate" the printed materials. J.A. 32–33. More

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detailed "medical information books" that were sometimes provided to patients at the time also suffered from similar problems—they would "easily become out-of-date, and may be lost or otherwise unavailable to the patient." J.A. 33. Whether in pamphlet or book form, these generic materials are not directed to the specific medical treatment instructions of any particular patient, and as such these printed materials are ill-suited to "assist the patient with the specific instructions deemed appropriate to their situation." *Id*.

In seeking to address this serious medical problem, Dr. Karpf had a fundamental insight: Patients are more likely to be compliant when they have ondemand access not only to generalized information about their disease and treatment, but also to the specific therapeutic regimen prescribed by their doctor, i.e., "the precise treatment instructions that the doctor issues to the patient." J.A. 33. Building on that insight, Dr. Karpf invented a multi-component electronic system that facilitates a patient's ability to access and comply with the treatment information she receives from her doctor. J.A. 33. The '053 application explains that a key feature of this system "is that the treatment instructions are available to patients upon demand." J.A. 35. Another key feature is the ability to measure patients' compliance in real-time by "tracking the patient[']s access to treatment information," and then issuing automatic reminder messages if necessary "to remind patients to comply with the treatment instructions." J.A. 36. Dr. Karpf's

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system is described in detail throughout the lengthy specification of the '053 application. *See generally* J.A. 29–166.

The invention works as follows. First, a patient reports to her doctor's appointment. She registers in the computer system, inputting information such as her name, mailing address, e-mail address, preferred language, and preferred contact details. Figure 6 provides "an example of the user-interface logon screen of the patient program" with which the patient interacts. J.A. 38; *see also* J.A. 139 (Fig. 6); J.A. 59 (explaining the fields in Figure 6); J.A. 35–36 (explaining that the "patient may specify a language preference" and may "specify the mechanism by which they will receive compliance reminder messages").

Next, the doctor examines the patient. Upon diagnosing the patient's condition, the doctor informs the patient of the diagnosis and treatment instructions. The doctor also "enter[s] into a treatment instructions database, at the time of the examination, the precise treatment instructions that the doctor issues to the patient." J.A. 33. The computer used by the doctor to enter the treatment instructions is termed the "medical personnel client." *See* J.A. 136 (Fig. 1); J.A. 145 (Fig. 12); J.A. 39 (explaining that Figure 12 is "an example of the user-interface of the medical personnel data entry program used to enter the patient diagnosis and treatment instructions"); J.A. 69–70 (explaining the fields in Figure 12). The treatment instructions are stored in a central computer called the

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"treatment server computer" which contains a database called the "treatment instructions database." *E.g.*, J.A. 136 (Fig. 1); J.A. 33.

Following the office visit, the patient logs on to the system—for example, from a home computer. As the specification explains, "[t]he patient may access all treatment instructions for all medical examinations from any computer that has a network connection to the Internet." J.A. 37. The patient selects a particular doctor's appointment from a listing of all of her appointments, and the system then outputs the treatment instructions issued by the doctor during that particular appointment. Figures 7 and 8 show examples of the user-interface screens of the patient program "showing the patient's office visits" and "showing the treatment instructions for a selected office visit." J.A. 38; *see also* J.A. 140–41 (Figs. 7 and 8). The patient may then view and comply with those instructions.

The system also features the ability to monitor patient compliance and send reminders to non-compliant patients. J.A. 36. The system monitors in real-time the patient's access of the post-examination treatment information, and using such access as a proxy for patient compliance, the system generates a measure of the patient's compliance. J.A. 36, 75. Patients exhibiting poor compliance receive a notification, such as an e-mail, reminding them to comply with their doctor's treatment instructions. J.A. 75, 149 (Fig. 16).

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The functionality of the invention disclosed in the '053 application is reflected in pending claims 26 through 37, all of which are at issue on appeal.² J.A. 432–34. Of these, claims 26 and 28 are independent claims.

Claim 28 recites an article of manufacture comprising a machine readable-storage medium, which stores a control program comprising steps including entering treatment information, determining the patient's access of that treatment information, and monitoring patient compliance based on such access:

- 28. An article of manufacture for use in monitoring patient compliance with prescribed treatment, the article of manufacture comprising a machine-readable storage medium having stored therein indicia of a plurality of machine-executable control program steps, the control program comprising the steps of:
 - (a) entering treatment information;
- (b) determining access of the treatment information by a patient; and
- (c) monitoring compliance of the patient based on access of the treatment information made by the patient in said determining access step (b).
- J.A. 433 (emphases added). Claim 28 thus requires entering "treatment information," which is then used in the subsequent steps—i.e., determining the patient's access of "the treatment information," and monitoring the patient's compliance based on the patient's access of "the treatment information." J.A. 433 (emphases added).

² Claims 1 through 25 were canceled during prosecution. J.A. 178, 406.

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Dependent claims 29 through 37 further limit claim 28. For example, claim 35 requires that the monitoring step (c) "is performed by measuring a rate at which the patient reviews treatment information." J.A. 434. Claim 36 adds step (d), "issuing a reminder to the patient based on the compliance of the patient monitored in said monitoring step (c)." *Id.* Claim 37 depends from claim 36 and further specifies how the reminder is issued. *Id.*

Claim 26, the other independent claim, involves the input by medical personnel of diagnosis and treatment information about a patient, followed by the output of such information over a network to the patient:

- 26. An electronic compliance promoter for use in promoting patient compliance with treatment instructions comprising:
- a medical personnel client, wherein said medical personnel client inputs from medical personnel diagnosis and treatment information regarding a patient following a medical appointment with the patient;
- a treatment server computer, wherein said treatment server computer receives diagnosis and treatment information from said medical personnel client; and
- a treatment instructions database, wherein said treatment instructions database stores the diagnosis and treatment information received from said treatment server computer;

wherein said treatment server computer, responsive to access of said treatment server computer by the patient, outputs to the patient over a network the diagnosis and treatment information corresponding to the patient.

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J.A. 432 (claim 26) (emphases added). Claim 26 thus requires that "diagnosis and treatment information" about a patient following a medical appointment is input by medical personnel into the computer system, and that, in response to a patient accessing the system, the system outputs to the patient "the diagnosis and treatment information"—i.e., the diagnosis and treatment information that was input from the medical personnel following the patient's medical appointment. J.A. 432 (emphasis added). Claim 27, which depends from claim 26, further specifies the information to be output to the patient.

B. The Soll Reference

The Soll patent is the only reference cited by the Board and the only reference at issue in this appeal.³ As explained below, the key issues with respect to Soll center on (1) whether it discloses a computer system that determines a patient's access of her post-examination treatment information; (2) whether it discloses a system that monitors the patient's compliance based on her access of such information; and (3) whether it discloses a computer that outputs such information to the patient over a network.

The Board treated Soll as prior art to the '053 application under 35 U.S.C. § 102(e), and for purposes of this appeal Dr. Karpf also treats it as such. During prosecution, however, Dr. Karpf indicated his ability to swear behind Soll. J.A. 366 (n.1). He reserves the right to do so in this case on remand or in any related application.

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Soll is directed to a computerized comprehensive patient management ("CPM") system located in a doctor's office. J.A. 546 (4:40); J.A. 550 (12:10–14) (stating that the system "resides in the medical clinic environment"); *see also* J.A. 518 (Fig. 1). Soll's CPM system contains several components. A "patient carrel" computer is located "in a private cubicle near the waiting room." J.A. 550 (12:55–56); J.A. 519 (Fig. 2). A "physician workstation" computer is "typically placed in the examining room." J.A. 550 (12:39–40). Other workstation computers located in the doctor's office may be accessed by the admitting clerk or the nurse. J.A. 550 (12:22–34). These computers are connected to a central "server/database." J.A. 550 (12:18–20).

The patient interacts with the system at the doctor's office under three circumstances: "[1] during the initial assessment sessions, [2] at exit interviews, and [3] upon clinic revisits." J.A. 547 (6:41–43); *see also* J.A. 551 (13:5–10); J.A. 520 (Fig. 3). These three interactions are described in detail throughout the Soll reference. *E.g.*, J.A. 548, 551–56 (7:14–8:29, 13:60–24:52) (describing the initial assessment); J.A. 548, 558 (8:29–38, 27:4–55) (describing the exit interview); J.A. 548, 558–59 (8:38–47, 28:5–29:17) (describing the revisit interview).

<u>Initial Assessment</u>. The patient's initial assessment session occurs prior to the doctor's examination. It consists of three software modules—triage, screening, and education. The "triage" questions are aimed at determining the principal

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reason that brings the patient to the clinic. J.A. 551 (14:35–37); J.A. 523 (Fig. 5A) (depicting the program run at the patient carrel, including the "Triage Q&A" module 340); J.A. 547 (5:47–48). The "screening" questions seek to characterize the patient's symptoms. J.A. 551 (14:48–50); J.A. 552 (16:22–34); J.A. 523 (Fig. 5A) (depicting the program run at the patient carrel, including the "Screening Q&A" module 360); J.A. 547 (5:47–48). And the education component involves loading an "education module" that "helps the patient understand[] the terms and issues they need to be informed about to accurately answer questions" during the initial assessment. J.A. 552 (15:29–34); J.A. 525 (Fig. 5C) (depicting the education module); J.A. 547 (5:51–52).

The answers given by the patient during Soll's triage, screening, and education modules are compiled to create a provisional "problem list" for use by the doctor as a starting point for the subsequent physical examination. J.A. 554 (19:3–8, 60–64). During the patient's physical examination, the doctor can access the patient's provisional problem list using the physician workstation to assist in diagnosing the patient and arriving at a treatment plan. J.A. 556 (24:53–56).

Exit Interview. Soll discloses that, following the doctor's examination, the patient "returns to the CPM patient carrel for the exit interview." J.A. 558 (27:4–5). The computer prompts the patient to answer a series of questions regarding the examination, such as whether the patient understands the condition and treatment

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plan, whether the patient intends to comply with the treatment (termed the patient's "compliance attitudes"), and whether the patient has anxiety about her illness. J.A. 558 (27:30–54, Table 6); J.A. 543 (Fig. 12) (depicting exit interview module).

After completing the exit interview but before leaving the doctor's office, the patient is given printed materials containing her physician's instructions and generalized health information: "Finally, the patient is given a printed health summary, including their problem list, physician and follow-up instructions, personalized health education materials, and a reference on local resources, such as further instruction, counseling, support groups, websites, and hotlines." J.A. 558 (27:13–18).

Revisit Interview. Upon returning to the clinic for a subsequent appointment, the patient interacts with the "revisit module" of Soll's system. J.A. 558 (28:8). The revisit module seeks information from the patient about developments since the last visit. For example, the patient is queried about the reason for the revisit, who initiated the revisit, and whether the patient has experienced new symptoms since the last visit. J.A. 558 (28:12–29).

When revisiting the clinic, the patient is "also asked about compliance with prescribed treatments and medications" from the initial visit. J.A. 558 (28:44–45). Furthermore, "[i]f the patient reports that she did not comply with any aspect of the treatment, reasons for noncompliance are sought." J.A. 558 (28:46–48). Soll

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refers to such questions during the revisit interview as "[p]atient self-reports on compliance." J.A. 558 (28:59). Importantly, Soll contains no indication that compliance information is automatically derived in real-time from the extent to which the patient accesses her treatment information between appointments.

Rather, compliance is assessed when the patient revisits the office for a subsequent appointment.

* * *

Nearly the entirety of Soll is directed toward patients' interactions with the CPM system during the initial assessment session, the exit interview, and revisiting the doctor's office. In addition to that lengthy and detailed disclosure, Soll also indicates in one brief passage that a patient may interact with the CPM system from home, in between doctor's appointments:

However, patients may access CPM in the interim *from home* (via the Internet or on a CPM CD-ROM or DVD) or at the provider organization *for triage, screening, or health education sessions*. Symptom updates are stored in the database. If CPM analysis of new patient information reveals a condition in need of prompt attention, the patient is instructed to seek care at the end of their CPM session. The patient's primary care physician is also notified of the patient's updated status via e-mail or an automated voice message or page generated by the inventive system.

J.A. 558 (27:58–67) (emphases added). That four-sentence passage—which forms the crux of the Board's decision on appeal—discloses that the patient may access Soll's system from home "for triage, screening, or health education sessions." *Id.*

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As noted above, those are the three modules that constitute the patient's initial assessment—i.e., the questions that the patient must answer prior to a doctor's examination.

Accordingly, this passage teaches that a patient—who has previously attended a doctor's appointment, undergone a *first* initial assessment, received a physical examination for that ailment, and exited the clinic—may at some later time log on to the CPM system from home and undergo *another* initial assessment to analyze *new* patient information. The passage further discloses that if, as part of that *additional* initial assessment, "new patient information reveals a condition in need of prompt attention," the patient can be instructed to seek immediate care. *Id.*Nowhere in this passage—or anywhere else in the Soll reference—does the patient use the system to access treatment information from the *previous* doctor's appointment.

C. The Board's Decisions

The examiner rejected claims 26 through 37 as anticipated by Soll under 35 U.S.C. § 102(e), and Dr. Karpf appealed that rejection to the Board. J.A. 418–36; J.A. 463–73. In a decision dated December 12, 2013, the Board affirmed the examiner's rejection of all claims other than claim 35 as anticipated by Soll. J.A. 1–16. The Board also entered two new grounds of rejection—a rejection of claim 35 under § 103(a) based on Soll alone, and a rejection of claim 28 under § 101. *Id.*

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Proceeding *pro se*, Dr. Karpf requested rehearing of all rejections. J.A. 480–89.⁴ The Board reconsidered its rejections but confirmed that, in its view, "claims 26–34, 36, and 37 [are] anticipated by [Soll]," "claim 35 is obvious over [Soll]," and "claim 28 is directed to non-statutory subject matter." J.A. 25.

Anticipation under § 102(e). The Board's anticipation decision relied principally on its finding that, in Soll, "patients may access the comprehensive patient management ('CPM') system in the interim between the exit interview and the patient's next visit to the doctor." J.A. 6 (citing Soll at 27:57–28:3 (J.A. 558)). In the Board's view, Soll teaches patient compliance with treatment information by disclosing that the patient can access the CPM system from home "for screening [to] reveal a condition in need of prompt attention":

[A]fter the exit interview, the patient is given a problem list with follow-up instructions (i.e., "treatment information") wherein the patient may subsequently access the CPM from home *for screening* and reveal a condition in need of prompt attention that causes the CPM to instruct the patient to seek care at the end of the session (i.e., "patient compliance").

J.A. 7 (emphasis added). The Board thus interpreted "patient compliance" to mean instructing the patient to seek care following initial "screening" of a condition.

In requesting rehearing of the Board's two new grounds of rejection, rather than requesting remand for further prosecution, Dr. Karpf exercised his right to have the new grounds reheard and made final for appeal. *See* 37 C.F.R. §§ 41.50(b)(2), 41.52(a)(1).

Regarding independent claim 26, the Board found that Soll teaches outputting to the patient over a network the patient's diagnosis and treatment information. J.A. 19–21.⁵ The Board again focused on Soll's disclosure that a patient may access the CPM system "from home" for purposes of "triage, screening, or health education sessions"—i.e., for an initial assessment of new patient information. J.A. 20 (citing Soll at 27:57–28:3 (J.A. 558)). Based on that disclosure, the Board found that Soll teaches a treatment server computer that "outputs diagnosis and treatment information over a network to a patient." J.A. 20.

Regarding independent claim 28, the Board reasoned that because Soll discloses that the patient logs on from a home computer to screen a new condition, and then the physician may be notified of the patient's updated status, Soll thus teaches monitoring the "compliance" of the patient:

Soll promotes patient compliance with treatment instructions by permitting the patient to access a CPM from a home computer where he or she can access information pertaining to triage, screening, and health education sessions (*see* Decision 5–6). Based on the patient accessing the CPM from home for screening, the CPM may instruct the patient to seek care at the end of the session (i.e., "patient compliance") (*see id.*). The patient's physician receives a notification of the patient's updated status as a means to monitor the compliance (*see* Soll, col. 27, ll. 22–24, 64–67).

The Board's original decision focused predominantly on the preamble of claim 26 and the claim's "medical personnel client" limitation. J.A. 4–8. The Board addressed Dr. Karpf's other arguments in its rehearing decision. J.A. 19–21.

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Accordingly, Soll is considered to disclose the steps [in claim 28] of "(b) determining access of the treatment information by a patient; and (c) monitoring compliance of the patient based on access of the treatment information," as claimed.

J.A. 21–22.⁶ The Board again interpreted "compliance" to mean instructing the patient to seek care following a pre-examination "screening" session. *Id.* at 22. The Board further found that because Soll discloses that a patient may log on to the system from home to perform an *initial assessment* of a *new condition*, and because the doctor may be sent a notification regarding this new condition, Soll discloses determining a patient's access of her post-examination treatment information and monitoring her compliance with that treatment information based on the extent to which the patient accesses it. J.A. 5–7, 21–22.

The Board also rejected dependent claims 36 and 37 under § 102(e). The Board found that Soll discloses the requirement in those claims of issuing a reminder to the patient based on her compliance, as measured through access of her *prior* treatment information, because the reference states that "[u]pon the patient providing *new information* that reveals a *new condition*, the patient is instructed to seek care." J.A. 12 (emphases added).

The Board's initial decision focused predominantly on claim 26 rather than claim 28. J.A. 4–8. The Board addressed Dr. Karpf's arguments regarding the patentability of claim 28 in its rehearing decision. J.A. 21–22.

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Obviousness under § 103(a). Claim 35 depends from claim 28 and adds the additional requirement of monitoring patient compliance "by measuring a rate at which the patient reviews treatment information." J.A. 434. Although the Board reversed the examiner's anticipation rejection of claim 35 over Soll, it entered a new obviousness rejection of that claim. J.A. 9–10, 12, 14–15, 25. The Board's analysis consisted of *assuming* that "Soll anticipates base claim 28," and then determining that the lone remaining feature of claim 35 would have been obvious to incorporate. J.A. 14 ("[W]e conclude incorporating *this feature* would have been obvious." (emphasis added)). The Board further determined that because Soll would have "inherently" time-stamped a patient's access of the CPM system, it must "necessarily" measure a rate at which a patient reviews her treatment information. *Id*.

Patent eligibility under § 101. Finally, the Board entered a new ground of rejection against claim 28 under § 101. J.A. 12–14, 25. The Board held that because claim 28 recites a "machine-readable storage medium," and because the specification does not expressly define that term to exclude a transitory signal, the claim is necessarily unpatentable under § 101. J.A. 13.

Still proceeding *pro se*, Dr. Karpf timely filed a notice of appeal to this Court. J.A. 490. Dr. Karpf subsequently retained current counsel of record.

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SUMMARY OF THE ARGUMENT

In its decision rejecting the pending claims for anticipation or obviousness, the Board focused myopically on a four-sentence passage in the Soll reference, misinterpreted what that passage in fact discloses, and then rejected all of the claims on that basis. The passage relied on by the Board states that a patient may access the computer system from home between appointments. That much is undisputed. The Board, however, *further* found that passage to teach (1) a system that determines a patient's access of her post-examination treatment information and monitors the patient's compliance with that information, as claim 28 requires, and (2) a system that outputs to a patient over a network her post-examination treatment information, as claim 26 requires. Soll does not disclose those limitations, and the Board's findings to the contrary lack substantial evidence.

The Board's decision rests on a fundamental misunderstanding of Soll. The Soll reference teaches that a patient may log on from home in order to perform an *initial assessment* of a *new condition* that she is experiencing. It does not disclose a system that permits a patient to access her treatment information from a *prior* medical examination. In fact, the *only* means by which Soll teaches that a patient receives her treatment information is by being given a *printed* summary prior to leaving the doctor's office. But that is the precise approach that Dr. Karpf's invention was designed to overcome—as his patent application explicitly states.

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J.A. 32 ("The current means to address the [patient compliance] problem primarily rely on pamphlets and/or packets of printed information appropriate to the patient's complaint While this has been helpful the approach has serious problems."). Because the Board's interpretation of Soll is entirely unsupported by the reference itself, the Board's anticipation rejection lacks substantial evidence. And because the Board's obviousness rejection is premised on its erroneous finding of anticipation and contains several additional errors, it requires reversal as well.

The Board's new ground of rejection of claim 28 under § 101 is also fundamentally flawed. The Board's analysis consisted solely of scanning the specification for a definition of "machine-readable storage medium" that expressly excluded a transitory signal and, finding none, rejecting the claim. The Board legally erred in at least three respects. First, the Board ignored that the claim is directed to an "article of manufacture comprising a machine-readable storage medium," and thus expressly recites a non-transitory statutory category of patent-eligible subject matter. Second, the specification contains no indication that this claim term should be read to include a transitory signal; in fact, it indicates just the opposite. Finally, the only opinion relied on by the Board in support of its decision directly undermines its determination that claim 28 claims ineligible subject matter. For these reasons, the Board's § 101 rejection also requires reversal.

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ARGUMENT

I. Standard of Review

The Court reviews the Board's factual findings for substantial evidence and its legal conclusions de novo. In re Gartside, 203 F.3d 1305, 1316 (Fed. Cir. 2000). Claim construction is a legal question, and this Court reviews the Board's "broadest reasonable" claim interpretation de novo. In re Abbott Diabetes Care *Inc.*, 696 F.3d 1142, 1148 (Fed. Cir. 2012). Anticipation under § 102 is a question of fact reviewed for substantial evidence. *In re Gleave*, 560 F.3d 1331, 1334–35 (Fed. Cir. 2009). Substantial evidence is "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." Gartside, 203 F.3d at 1312 (quoting Consol. Edison Co. v. NLRB, 305 U.S. 197, 229 (1938)). Obviousness under § 103(a) is a legal conclusion with underlying factual findings. Leo Pharm. Prods., Ltd. v. Rea, 726 F.3d 1346, 1353 (Fed. Cir. 2013). This Court reviews the legal conclusion *de novo* and the Board's underlying factual findings for substantial evidence. *Id.* Whether a claim is directed to patent-eligible subject matter under § 101 is a question of law that this Court reviews de novo. In re Nuijten, 500 F.3d 1346, 1352 (Fed. Cir. 2007).

II. The Pending Claims Are Patentable over Soll

A. Soll Does Not Anticipate Claim 28 and Its Dependent Claims

Independent claim 28 and dependent claims 29–34, 36, and 37 require

(1) determining a patient's access of her previously entered treatment information,

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and (2) monitoring the patient's compliance based on her access of that information. Soll, however, discloses *neither* of those limitations. The standard for anticipation is well-established and exacting: "It is axiomatic that for anticipation, *each and every* claim limitation must be explicitly or inherently disclosed in the prior art." *In re NTP, Inc.*, 654 F.3d 1279, 1302 (Fed. Cir. 2011) (collecting cases). Because the Board's anticipation decision falls far short of this standard, reversal of these rejections is required. *See id.* ("Keeping in mind that these are anticipation, not obviousness rejections, the failure to disclose this claim element requires reversal of these rejections.").

1. "The Treatment Information" in Steps (b) and (c) of Claim 28 Refers to "Treatment Information" Entered in Step (a)

Claim 28 requires "(a) entering treatment information," followed by "(b) determining access of *the* treatment information by a patient" and "(c) monitoring compliance of the patient based on access of *the* treatment information" J.A. 433 (emphases added). As a matter of claim construction, basic patent drafting principles, and simple grammar, "*the* treatment information" in steps (b) and (c) must refer back to the previously entered "treatment information" in step (a).

The construction of a claim term must account for its antecedent basis. *See, e.g.*, *Haemonetics Corp. v. Baxter Healthcare Corp.*, 607 F.3d 776, 781–82 (Fed. Cir. 2010) (rejecting a claim construction that "ignores the antecedent basis" of the

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disputed claim term and thus "fails to give effect to the claim language"); *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1356–57 (Fed. Cir. 1999) (adopting a particular claim construction because it "avoids any lack of antecedent basis problem"). The requirement of an antecedent basis is also enforced by the Patent Office during examination. *See, e.g., Energizer Holdings, Inc. v. Int'l Trade Comm'n*, 435 F.3d 1366, 1370–71 (Fed. Cir. 2006) ("The requirement of antecedent basis is a rule of patent drafting, administered during patent examination."); MPEP § 2173.05(e) (7th ed. July 1998) (explaining that a claim lacks antecedent basis if it refers to "the lever" but contains no earlier recitation of a "lever"). Here, it is beyond dispute that the only possible antecedent basis for "*the* treatment information" in steps (b) and (c) of claim 28 is the previously entered "treatment information" in step (a).

That construction is also supported by the written description of the '053 application. Upon examining the patient, the doctor "enter[s] into a treatment instructions database, *at the time of the examination*, the precise treatment instructions that the doctor issues to the patient." J.A. 33 (emphasis added). Following the doctor's appointment, the patient then logs on to the system to access "[t]he treatment information 816 for the selected appointment." J.A. 63; *see also* J.A. 141 (Fig. 8). The relevant portion of Figure 8, depicting "[t]he treatment

information 816," is shown below:

816	Seq	Time	Description	
	1	1 mo	Take insulin each day	
	2	3 mo	Blood sugar test and liver function at lab	
	3	3 mo	Return for consultation and followup with Dr.	

J.A. 141 (Fig. 8); J.A. 63; J.A. 38 ("Fig. 8 is an example of the user-interface screen of the patient program showing the treatment instructions for a selected office visit."). The specification thus teaches that the doctor *first* enters a patient's treatment information at the time of the examination, and *then*, following the examination, the patient accesses the treatment information. Plainly, the treatment information that is accessed by the patient in steps (b) and (c) of claim 28 is the information entered by the doctor in step (a) at the time of the physical examination.

Under the only reasonable interpretation of claim 28, therefore, the patient's access of "the treatment information" in steps (b) and (c) involves a patient accessing the previously entered "treatment information" from step (a). If the patient does not access the treatment information entered in step (a), then the limitations of claim 28 (or its dependent claims, all of which incorporate the limitations of claim 28) are not met.

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2. Soll Does Not Disclose Determining Access of the Treatment Information by a Patient

Nowhere does Soll disclose that a patient may use Soll's system to access previously entered treatment information, as step (b) of claim 28 requires. The only time that the patient in Soll is given her treatment information is at the conclusion of the exit interview, when she is leaving the doctor's office. J.A. 557 (26:57–58) ("Patients are given personalized instructions and education material when they leave the clinic." (emphasis added)). But, importantly, the patient is not given access to her treatment information electronically. Rather, the information is given to the patient as "a printed health summary" that includes the patient's "problem list, physician and follow-up instructions, personalized health education materials, and a reference on local resources, such as further instruction, counseling, support groups, websites, and hotlines." J.A. 558 (27:14–18) (emphasis added).

This point underlies a key error in the Board's analysis. In view of Soll's express disclosure that patients receive treatment information only as a printed summary, rather than in an electronic format, it defies reason to interpret Soll as disclosing a computer program capable of "determining access of the treatment information by a patient." J.A. 433 (claim 28). It would be a special computer program indeed that could determine access by a patient of a printed piece of paper. Soll, in fact, discloses nothing about determining a patient's access of her

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post-examination treatment information. Simply put, the Board's reading of Soll is incorrect and unsupported by substantial evidence.

Rather than acknowledging that Soll is directed only to a "printed summary" of treatment information, the Board instead relied on Soll's disclosure that a patient may access the CPM system from home for "triage, screening, and health education sessions." J.A. 22–23; see also J.A. 558 (Soll at 27:58–67). But that passage does not disclose determining a patient's access of previously entered treatment information. To the contrary, the computerized "triage, screening, or health education sessions" that may be conducted from home constitute an *initial* assessment of a patient for a new condition, which occurs before the patient is examined by a doctor for the new condition, and before treatment information is entered for the new condition.

a. Triage, Screening, and Health Education Sessions Occur *Before* Treatment Information Is Entered

As Soll explains, the "first component" of the system entails "assessing the patient's presenting health problems" using a computerized question-and-answer assessment. J.A. 548 (7:14–17). Soll states that this "initial CPM assessment [occurs] *before* seeing the physician." J.A. 551 (13:5–6) (emphasis added). Soll further explains that this initial assessment contains three modules—triage, screening, and health education sessions.

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The "triage" questions are aimed at determining "the principal reasons that bring the patient to the clinic, thereby informing the system where to being [sic, begin] asking more specific questions." J.A. 551 (14:35–39). Following triage, "[t]he next sequences" entail posing to the patient a series of "screening" questions, which "pursue symptoms elicited in the triage module." J.A. 552 (16:22–24); see also J.A. 551 (14:48–50). Finally, an "education module" is loaded "at selected point[s] in the interview process." J.A. 552 (15:29–31). Soll explains that "[t]his education module helps the patient understand[] the terms and issues they need to be informed about to accurately answer questions" during the triage and screening modules. J.A. 552 (15:32–34). The purpose of Soll's initial computerized patient assessment—which occurs before the patient even sees the doctor for a given condition—is to gather "patient assessment data," which the system then "analyzes" to create a "provisional problem list." J.A. 549 (10:45– 47); see also J.A. 554 (19:3–8) (describing the "[i]nitial identification of provisional problems" as "the first major step" in the process).

After the patient's initial assessment is complete and the provisional problem list is generated, the doctor logs on to the system and reviews the provisional problem list. Soll discloses that the patient's "provisional problems . . . will be presented as the CPM problem list for physician consideration," J.A. 554 (19:62–64), and that "[b]efore or at the outset of the patient interview [by the

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physician], the physician accesses the CPM physician module to review the patient information as collected" during the initial assessment, J.A. 556 (24:53–55).

Only at the end of this process, after the doctor physically examines the patient, does the doctor enter the treatment information, which is necessarily based on the physical examination. Soll discloses that "[a]fter completion of the physical examination, the physician reviews and edits the problem list," J.A. 557 (26:17–18) (emphasis added), and that "[o]nce problems are defined, management options . . . are displayed for selection" by the doctor, J.A. 557 (26:30–32). The doctor's selected management options—which include "diagnostic tests," "subspecialty referrals," and "therapeutic options including indicated drugs"—constitute the doctor's treatment information for the patient. J.A. 557 (26:36–43).

Accordingly, Soll discloses that triage, screening, and health education sessions are the three modules of the initial assessment, which precedes the entry of treatment information for a particular condition.

b. Soll's Passage About Home Access Merely Discloses Another Initial Assessment

The Board fundamentally misunderstood the passage in Soll stating that a patient may access the computerized CPM system from home. J.A. 6–7, 21–22. That passage does not teach that the patient may access her *previously entered* treatment information—or, indeed, any treatment information at all. Rather, it

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discloses that the patient may initiate *another* initial assessment from home based on a *new* condition.

The passage in Soll states that "patients may access CPM in the interim [between appointments] from home . . . for triage, screening, or health education sessions." J.A. 558 (27:58–61) (emphasis added). But, as explained above, Soll teaches that triage, screening, and health education sessions constitute the *initial* assessment portion of Soll's system—which occurs *prior to* the doctor's examination of the patient and *prior to* the doctor's entry of any treatment information for that condition. See supra Part II.A.2.a. The Board thus failed to appreciate that this brief passage discloses the ability of Soll's system to perform another *initial* assessment of the patient from home, based on new symptoms experienced by the patient.

Immediately following the disclosure by Soll that a patient may access the system from home, Soll confirms that home access is for the purpose of assessing a patient's *updated* status based on *new* information—not previously entered treatment information:

Symptom updates are stored in the database. If CPM analysis of new patient information reveals a condition in need of prompt attention, the patient is instructed to seek care at the end of their CPM session. The patient's primary care physician is also notified of the patient's updated status via e-mail or an automated voice message or page generated by the inventive system.

J.A. 558 (27:61–67) (emphases added).

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The reference in Soll to home access therefore does not disclose a patient accessing *prior* treatment information from a *previous* doctor's appointment. Nor does it disclose determining access of such information. Rather, in discussing "[s]ymptom updates," "new patient information," and "the patient's updated status," Soll discloses the ability of its system to perform a *new* initial assessment, after which a patient may be "instructed to seek care" if the new symptoms so warrant. *Id*.

For these reasons, Soll does not disclose determining access of the treatment information by a patient, as step (b) of claim 28 requires.

3. Soll Does Not Disclose Monitoring Compliance of the Patient Based on Access of the Treatment Information

Similarly, the Board's determination that Soll discloses step (c) of claim 28 also lacks substantial evidence. *See* J.A. 433 (requiring "(c) *monitoring compliance* of the patient based on access of the treatment information made by the patient in said determining access step (b)" (emphasis added)).

As explained above, Soll discloses only that "the patient is given a *printed* health summary" containing treatment information. J.A. 558 (27:13–14) (emphasis added). Soll contains no disclosure indicating that the computerized system is somehow capable of monitoring the patient's compliance based on her access of this "printed" summary, and nothing cited by the Board suggests otherwise. There is also no disclosure in Soll indicating that the patient is supplied

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with treatment information electronically, let alone a disclosure of a means by which the system monitors the patient's compliance based on access of such information.

In an unsuccessful attempt to support its conclusion that Soll discloses "monitoring compliance of the patient," J.A. 433 (claim 28), the Board states that when the patient accesses Soll's system from a home computer, the system may "instruct the patient to seek care at the end of the session (i.e., 'patient compliance')," J.A. 7 (Board Decision); J.A. 22 (Rehearing Decision). The Board's interpretation of "compliance" misses the mark. Seeking care for a new condition is not "compliance" with *previously entered* treatment instructions concerning a *prior* condition. Rather, as expressly defined in the '053 application and in accordance with its general understanding in the field, "compliance" means that the patient follows the doctor's *post-examination* treatment instructions. J.A. 30 ("There is a significant problem with patients' failing to follow a medical practitioners post-examination treatment instructions. The terminology we use for this is *compliance*." (emphases added)).

Contrary to the Board's characterizations, Soll discloses that a patient logs on to the CPM system from home to provide "new patient information," and based on the system's analysis of that new information the patient may be instructed to seek care: "If CPM analysis of new patient information reveals a condition in need

of prompt attention, the patient is instructed to seek care at the end of their CPM session." J.A. 558 (27:61–64). An instruction to seek care based on new patient information is not "compliance of the patient" with post-examination treatment information, as required by claim 28. J.A. 433 (claim 28); J.A. 30. The Board's decision is unsupported by substantial evidence.

4. Soll Does Not Anticipate the Claims that Depend from Claim 28

The foregoing analysis regarding the novelty of independent claim 28 over Soll applies equally to claims 29–34, 36, and 37, each of which depends from claim 28 and incorporates all of its limitations. *See* 35 U.S.C. § 112 ¶ 4 (Supp. 2011) ("A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers."). Because Soll does not anticipate independent claim 28, Soll also does not anticipate the claims that depend from claim 28. *See, e.g., Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1296 (Fed. Cir. 2002); *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1576 n.36 (Fed. Cir. 1987). For the same reasons as for claim 28, therefore, the

This passage also states that a patient may access the system from home "for triage, screening, or health education sessions." J.A. 558 (27:60–61). As explained above, that statement refers to an initial assessment of a patient's condition, not compliance with post-examination treatment instructions. *See supra* Part II.A.2.b.

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Board's anticipation rejections of those dependent claims lack substantial evidence and require reversal.

In addition, the Board's decision affirming the rejection of dependent claims 36 and 37 fails for still other reasons. Claim 36 requires "(d) issuing a reminder to the patient based on the compliance of the patient" who is monitored in step (c). J.A. 434. Claim 37 depends from claim 36 and includes the same limitation. *Id.* Again referencing the passage in Soll regarding home access, the Board held that the limitations of claims 36 and 37 are disclosed because "[u]pon the patient providing new information that reveals a new condition, the patient is instructed to seek care." J.A. 12 (citing Soll at 27:62–64 (J.A. 558)). But claims 36 and 37 require issuing a reminder to the patient based on the monitored compliance of the patient with the previously entered treatment information. See J.A. 433–34 (claims 28, 36, 37). By contrast, the passage in Soll teaches instructing a patient to seek care based on "new patient information [that] reveals a condition in need of prompt attention." J.A. 558 (24:62–63). Instructing a patient to seek care for a new condition is not a disclosure of issuing a reminder to a patient based on the patient's monitored compliance with *previously entered* treatment information. Compare J.A. 558 (27:59–64), with J.A. 30 (explaining that patient "compliance" means following "post-examination" treatment information). For this additional reason, the Board's decision rejecting claims 36 and 37 lacks substantial evidence.

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B. The Board's Obviousness Rejection of Claim 35 Is Legally Flawed

In a new ground of rejection entered for the first time on appeal, the Board rejected claim 35 as obvious over Soll alone. J.A. 12, 14–15, 25. Claim 35 depends from independent claim 28, adding that "step (c) [of claim 28] is performed by measuring a rate at which the patient reviews treatment information." J.A. 434. Because the Board's obviousness analysis of claim 35 was founded on, and thus infected by, its erroneous anticipation analysis of claim 28, it too requires reversal. In addition, the Board's decision suffers from other deficiencies, all of which render its obviousness conclusion legally erroneous.

First, the Board's obviousness analysis of claim 35 is fatally intertwined with its erroneous anticipation rejection of claim 28. Because claim 35 depends from claim 28, it necessarily includes all of the limitations of claim 28. See 35 U.S.C. § 112 ¶ 4 (Supp. 2011). In its obviousness rejection, however, the Board did not analyze each limitation of claim 35. Instead, it took a shortcut. It expressly relied on its prior conclusion that Soll anticipates claim 28, and then focused solely on the one remaining feature of claim 35, concluding that "this feature would have been obvious":

We find Soll anticipates base claim 28. Soll does not specifically disclose measuring the rate at which the patient reviews treatment information (see Soll col. 27, ll. 60–61). However, upon review of Soll's teachings, we conclude incorporating this feature would have been obvious to an ordinarily skilled artisan at the time of the invention in light of Soll.

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J.A. 14 (emphases added). Thus, aside from the one limitation involving "measuring a rate at which the patient reviews treatment information," the entirety of the Board's analysis of claim 35 was based on its finding that Soll anticipates claim 28.

The Board's rejection is unsound. As explained at length above, Soll does *not* anticipate claim 28. *See supra* Part II.A. Because the Board's obviousness rejection rested in substantial part on a faulty premise, it is irreparably flawed and should be reversed. *See, e.g., In re Giannelli*, 739 F.3d 1375, 1379–81 (Fed. Cir. 2014) (reversing an obviousness rejection where the Board's analysis began with a faulty premise).

Second, the Board legally erred in analyzing claim 35 for obviousness. In rejecting a claim as obvious, the Board must analyze the claimed subject matter "as a whole." 35 U.S.C. § 103(a). The Board, however, did not analyze claim 35 as a whole. Instead, it merely evaluated the obviousness of one feature of claim 35.

J.A. 14 (holding that "incorporating this feature would have been obvious" (emphasis added)). The Board's analysis, therefore, is legally improper. See Sanofi-Synthelabo v. Apotex, Inc., 550 F.3d 1075, 1086 (Fed. Cir. 2008) ("The determination of obviousness is made with respect to the subject matter as a whole, not separate pieces of the claim."); Hartness Int'l Inc. v. Simplimatic Eng'g Co., 819 F.2d 1100, 1108 (Fed. Cir. 1987) (reversing an obviousness analysis because

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"the district court erred in failing to consider that dependent claim 3 included all the limitations of [independent] claim 1").

Third, Soll does not, as the Board held, render obvious the requirement of "measuring a rate at which the patient reviews treatment information." J.A. 434 (claim 35). As explained above, Soll does not disclose the limitations in claim 28 requiring a patient's "access of the treatment information." See supra Parts II.A.2. & II.A.3. And because a patient cannot review information without first accessing it, Soll does not teach or suggest "measuring a rate at which the patient reviews" such information, as claim 35 requires.

The Board's obviousness rejection relied exclusively on a single sentence in Soll. J.A. 14 (citing Soll at 8:39–44 (J.A. 548)). That sentence, found in the "Summary of the Invention" section, states that when the patient returns to the clinic, her "compliance" is "assess[ed]" as part of Soll's revisit module. J.A. 548 (8:40); *see also id.* (8:30). Soll describes this revisit module in far greater detail in the "Detailed Description" section. J.A. 558 (28:5–29:17). There, Soll explains that when the patient returns to the clinic, she is "asked about compliance" as part of the revisit module. J.A. 558 (28:7, 44–45). Soll refers to this question-and-answer process as "self-reports on compliance." J.A. 558 (28:59).

The only sentence in Soll relied on by the Board in its obviousness rejection, therefore, merely teaches that the patient may be asked questions about her

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compliance when she returns to the clinic. It does not suggest a computer program for "(c) monitoring compliance of the patient based on access of the treatment information," and it certainly does not suggest a program wherein monitoring step (c) is performed by "measuring a rate at which the patient reviews treatment information." J.A. 433–34 (claims 28, 35). Merely asking patients about their compliance after they have returned to the clinic does not advance any of the key objectives of the '053 application, such as the ability to electronically measure patients' compliance in real-time by "tracking the patient[']s access to treatment information," and then issuing automatic reminder messages if necessary "to remind patients to comply with the treatment instructions." J.A. 36. Simply put, the Board has not enunciated any plausible reason why a person of ordinary skill in the art would have modified Soll to arrive at the subject matter of claim 35. See Giannelli, 739 F.3d at 1380.

Finally, the Board's obviousness rejection seeks to fill gaps in Soll's disclosure through improper reliance on the doctrine of inherency. The Board asserted that Soll renders obvious measuring a rate at which the patient reviews treatment information because "Soll's system would inherently time stamp the patient's access of the CPM system," and such systems either "necessarily" record access time "or at least suggest" tracking such access information. J.A. 14–15 (emphasis added). The Board's reliance on inherency is misplaced. Inherency

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applies only if "the limitation at issue necessarily must be present, or the natural result of the combination of elements explicitly disclosed by the prior art." *PAR Pharm., Inc. v. TWI Pharm., Inc.*, --- F.3d ---, No. 2014-1391, 2014 WL 6782649, at *7 (Fed. Cir. Dec. 3, 2014).

The Board's reasoning fails to meet the "high standard" of inherency. *Id.* The Board's finding of inherent time-stamping is not supported by the passage from Soll that it cited. See J.A. 14 (citing Soll at 8:39-44 (J.A. 548)). But even if it were, time-stamping the patient's access of the CPM system is not the same as measuring the frequency at which the patient reviews treatment information. Soll's CPM system contains several modules (see supra pp. 10–14), and even assuming it permitted the patient to access her treatment information (which it does not; see supra Part II.A.2.), that would be just one of several ways in which the patient might interact with the system. It is not enough for purposes of inherency that the system purportedly time-stamps the patient's "access of the CPM system" if the patient may or may not access her treatment information while accessing the system. J.A. 14–15; see also In re Rijckaert, 9 F.3d 1531, 1534 (Fed. Cir. 1993) ("The mere fact that a certain thing may result from a given set of circumstances is not sufficient [to establish inherency]." (brackets in original) (quotation marks omitted)). The Board's misplaced finding does not amount to substantial evidence

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that Soll's system *necessarily* performs "measuring a rate" at which the treatment information is reviewed.

For each of these reasons, the Board's obviousness rejection is legally erroneous and should be reversed.

C. Soll Does Not Anticipate Claims 26 and 27, Because It Does Not Disclose Outputting to the Patient over a Network the Patient's Diagnosis and Treatment Information

For reasons similar to those described above for claim 28, the Board's decision rejecting independent claim 26 and dependent claim 27 as anticipated by Soll also lacks substantial evidence. Claim 26 requires a treatment server computer that receives diagnosis and treatment information, "wherein said treatment server computer, responsive to access of said treatment server computer by the patient, *outputs to the patient over a network the diagnosis and treatment information corresponding to the patient.*" J.A. 432 (emphasis added). Claim 27 depends from claim 26 and also contains this requirement. J.A. 432–33. Nothing in Soll describes this requirement, and the Board's decision to the contrary should be reversed.

As an initial matter, the term "the diagnosis and treatment information" in the "wherein" clause of claim 26 refers back to "diagnosis and treatment information regarding a patient following a medical appointment with the patient" in the prior "medical personnel client" clause. *Id.* (emphasis added). Claim 26

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therefore requires that the treatment server computer output to the patient over a network the patient's diagnosis and treatment information "following a medical appointment with the patient." *Id.*; *see also supra* Part II.A.1. (discussing the need to account for antecedent basis in construing a claim term). It is not enough for a computer simply to output *any* diagnosis and treatment information; claim 26 is met only if the computer outputs to the patient over a network the patient's diagnosis and treatment information *stemming from a prior medical appointment* with the patient. Nothing in Soll discloses this requirement.

First, the Board again cited the passage in Soll stating that the patient may access the system from home. J.A. 20 (citing Soll at 27:57–28:3 (J.A. 558)). But the Board offered no explanation how Soll's "triage, screening, or health education sessions" output any diagnosis and treatment information, let alone such information stemming from a patient's prior medical appointment. See J.A. 20. Nor could it. As explained above, that passage in Soll merely discloses the performance of another initial assessment of the patient from home, based on new symptoms experienced by the patient, prior to any medical appointment concerning those new symptoms. See supra Part II.A.2.b.; see also J.A. 558 (27:61–67) (discussing the analysis of "new patient information"). It says nothing

The Board addressed Dr. Karpf's argument on this point only in its rehearing decision, *see* J.A. 19–20, not its original decision, *see* J.A. 4–7.

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whatsoever about, and certainly does not teach, outputting prior diagnosis and treatment information. Accordingly, this passage does not constitute substantial evidence in support of the Board's anticipation decision.

Second, the Board cited a passing phrase in Soll's Abstract stating that the system "seeks to educate the patient." J.A. 20 (citing Soll at Abstract (J.A. 517)). That statement appears to refer to Soll's "education module," which, as explained above, is part of the pre-examination initial assessment. See J.A. 552 (15:29–47) (discussing the education module); J.A. 525 (Fig. 5C) (depicting the education module program); see also supra pp. 10–11 (discussing the education module component of the initial assessment). Because it occurs prior to a medical examination, Soll's education module could not possibly entail outputting to a patient her diagnosis and treatment information following a medical appointment with the patient. Soll's Abstract therefore does not support the Board's anticipation decision regarding claims 26 and 27.

Third, referencing Figure 1 of Soll, the Board observed that Soll's system includes a patient module that is linked both to a physician module and a "server/database." J.A. 20. The Board then concluded summarily that, "[t]herefore, we find Soll teaches a treatment server computer (server/database 30, FIG. 1) outputs diagnosis and treatment information over a network to a patient (patient carrel 10, FIG 1, or patient's home computer) in response to access by the

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patient, as claimed." J.A. 20 (citing Soll, Fig. 1 (J.A. 518)). But Figure 1 merely depicts a simple "hardware block diagram" of the components of Soll's system.

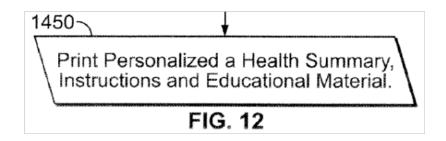
J.A. 547 (5:37–38); see also J.A. 518 (Fig. 1). Nowhere in Figure 1—or anywhere else in Soll—is it disclosed that a computer outputs to the patient over a network the patient's diagnosis and treatment information following a medical appointment with the patient. Figure 1, therefore, does not support the Board's decision regarding claims 26 and 27.

Finally, on rehearing, the Board asserted that "although not relied upon in affirming the Examiner," step 1450 in Figure 12 of Soll "shows CPM system server/database providing the patient with such diagnosis and treatment information." J.A. 20–21 (citing Soll, Fig. 12 (J.A. 543)). This last-ditch attempt to rehabilitate Soll should be rejected. As an initial matter, because this disclosure was "not relied upon in affirming the Examiner," J.A. 20, it is not an appropriate basis for affirming the Board's decision here. See In re Leithem, 661 F.3d 1316, 1319, 1321 (Fed. Cir. 2011) ("The Board cannot play it so fast and loose in affirming an examiner's rejection that it disregards procedural safeguards afforded to the applicant.").

Moreover, the Board's assertion is simply wrong. Step 1450 of Figure 12 does not, as the Board suggests, disclose that Soll's treatment information is provided "over a network," as claim 26 requires. To the contrary, step 1450

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confirms what the rest of Soll's specification discloses—that the treatment information is provided to the patient only in a *printed*, not electronic, format:



J.A. 543 (Fig. 12, step 1450); *see also* J.A. 558 (27:13–14) (stating that, upon completing the exit interview at the patient carrel, "the patient is given a *printed* health summary" (emphasis added)); *see supra* Part II.A.2.

In the context of the '053 application, there is a vital and material difference between providing a patient with a print-out of her diagnosis and treatment information versus outputting that information "over a network" to the patient in an electronic format. The principal objectives of Dr. Karpf's invention include promoting patient compliance by (1) facilitating the patient's access to her doctor's treatment information, (2) monitoring her access of that treatment information, and (3) based on such monitoring, issuing a reminder to the patient to comply with her treatment information. J.A. 33–37. As the specification of the '053 application explains, providing a patient with printed diagnosis and treatment information does not further any of those goals. J.A. 32–33.

The specification of the '053 application expressly points out the "serious problems" associated with providing patients "pamphlets and/or packets of printed

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information" about their condition. J.A. 32; see also supra pp. 3-4. For example, electronic information may be easily updated or revised to reflect changed treatment guidelines, but "more recent medical advances and treatment guidelines may easily outdate the information" provided in a printed summary. J.A. 32–33; see also J.A. 34 (explaining that outputting information "over a network" permits access to "the most up-to-date treatment guidelines"). Furthermore, unlike a printout which may be misplaced or unavailable, outputting information in an electronic format over a network means that "[t]he patient may access all treatment instructions for all medical examinations from any computer that has a network connection to the Internet." J.A. 37. Outputting the information over a network for patient access also enables "tracking the patient[']s access to treatment information and using it to generate a patient's measure of compliance," which in turn permits the system to remind non-compliant patients "to comply with the treatment instructions." J.A. 36. The '053 application describes these capabilities as "important" and "key" to the function of the invention—and there is no question that they could not be achieved if the patient were merely given printed information. *E.g.*, J.A. 36–37.

In short, outputting diagnosis and treatment information "over a network" to the patient is a critical aspect of Dr. Karpf's invention. Soll's disclosure that "the patient is given a printed health summary" not only fails to satisfy the requirements Case: 14-1773 Document: 16 Page: 52 Filed: 01/09/2015

of claims 26 and 27 but, in fact, altogether thwarts the advantages of the claimed invention.

For all of these reasons, the Board's conclusion that Soll discloses each and every limitation of claims 26 and 27 should be rejected as lacking substantial evidence.

III. Claim 28 Is Patent-Eligible under § 101 Because It Does Not Encompass a Transitory Signal

In addition to its erroneous affirmance of the examiner's § 102 rejections, the Board also entered a new ground of rejection under § 101 against independent claim 28 (but not its dependent claims). J.A. 12–14, 23, 25. The Board's rationale for this rejection was that "the recited 'machine-readable storage medium' encompasses transitory propagating signals," which "are unpatentable under § 101." J.A. 13 (citing *Nuijten*, 500 F.3d at 1355). The Board's holding that the claimed "machine-readable storage medium" encompasses transitory signals is wrong as a matter of law. Not only does the Board's decision misinterpret that claim term in isolation and ignore that the claim is directed to a patent-eligible "article of manufacture," it also disregards the specification as a whole, and it relies on Board precedent that does not support—and, indeed, undermines—its rejection under § 101.

A. The Board Disregarded that the Claim Is Directed to a Patent-Eligible "Article of Manufacture"

The Board committed several errors in concluding that claim 28 falls outside any statutory category of patent-eligible subject matter. The Board's first error was to ignore the claim term immediately preceding the term at issue. By its terms, claim 28 is not directed to a "machine-readable storage medium" but rather to an "article of manufacture comprising" such a medium. J.A. 433. Thus, "machine-readable storage medium" cannot be read in isolation, but must be understood as a component of an "article of manufacture." Importantly, a "manufacture" is *expressly designated by statute* as patent-eligible subject matter. *See* 35 U.S.C. § 101 (designating as patent-eligible "any new and useful process, machine, *manufacture*, or composition of matter" (emphasis added)). Moreover, this Court has expressly held—in the very case that first held that "transitory" signals are unpatentable under § 101—that an "article of manufacture" is *by*

The inquiry here is like the one faced by the Court in *Nuijten*, namely, whether the claim "is covered by *any* statutory category" under § 101. *See* 500 F.3d at 1354. In *Nuijten* the answer was *no*, because the claims merely recited "A signal . . ." and thus fell outside any of the four categories of patent-eligible subject matter. *Id.* at 1351. The *Nuijten* claims did *not*, as the claims do here, claim "An article of manufacture . . . ," thus placing them squarely within the scope of § 101. *See id.* at 1356 & n.6. Importantly, unlike the analyses in many recent § 101 cases, the Board did *not* determine that the claims here recite a statutory category but nevertheless fall into one of the three judicially recognized exceptions. *See*, *e.g.*, *Alice Corp. Pty. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2354 (2014).

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definition a tangible, non-transitory object, not an ephemeral signal. See Nuijten, 500 F.3d at 1356 ("[D]efinitions address 'articles' of 'manufacture' as being tangible articles or commodities. A transient electric or electromagnetic transmission does not fit within that definition."); see also Diamond v.

Chakrabarty, 447 U.S. 303, 308, (1980) ("[T]his Court has read the term 'manufacture' in § 101 in accordance with its dictionary definition to mean 'the production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by hand-labor or by machinery." (quoting Am. Fruit Growers, Inc. v. Brogdex Co., 283 U.S. 1, 11 (1931))). The Board erred by ignoring the language of claim 28, which is expressly directed to a statutory category under § 101 and, by its terms, excludes the transitory signals that were the basis for the Board's rejection.

The Board's decision cites guidance issued by the Patent Office, but that guidance does not support the Board's decision here. *See* J.A. 13 (citing David J. Kappos, *Subject Matter Eligibility of Computer Readable Media*, 1351 Off. Gaz. Pat. Office 212 (Feb. 23, 2010), *available at* 2010 WL 5544129 ("*Subject Matter Eligibility*")). According to that guidance, a claim reciting "a computer readable medium" or a like phrase is "per se" patent-ineligible under § 101. *Subject Matter Eligibility*, at *1. The guidance "suggests," however, that an applicant may avoid a § 101 rejection "by adding the limitation 'non-transitory' to the claim," whether or

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not that term is found in the specification. *Id.* (explaining that "[s]uch an amendment would typically not raise the issue of new matter, even when the specification is silent" in that respect).

The point of the agency's guidance, therefore, is to permit an applicant to bring his claim within the realm of patent-eligible subject matter by adding a claim term that excludes transitory signals. By directing claim 28 to an "article of manufacture," Dr. Karpf has done exactly that. See Nuijten, 500 F.3d at 1356-57 & n.6; see also 35 U.S.C. § 101. If, on the other hand, the Patent Office maintains that it will accept under § 101 claims that recite "non-transitory," but it will reject claims that recite an "article of manufacture," then the agency's policy is arbitrary, capricious, and simply nonsensical. Both of those terms have the effect of excluding transitory signals, and thus limit the claim to patent-eligible subject matter. Indeed, if § 101 is satisfied by reciting the limitation "non-transitory," then surely it is sufficient under § 101 to recite the very term that the statute itself states is patent-eligible. ¹⁰ In all events, the Board's decision rejecting claim 28 under § 101 is legally erroneous and should be reversed.

The Patent Office's own § 101 training materials support this precise point. The published materials state that excluding transitory signals from a claim "by adding 'non-transitory' to modify the computer readable media" is "simply one option" to avoid ineligibility under § 101; the "Applicant can choose other ways to amend the claim" and achieve the same result. USPTO, Evaluating Subject Matter Eligibility Under 35 U.S.C. § 101: August 2012 Update 14 (2012), http://www.uspto.gov/patents/law/exam/101 training aug2012.pdf (emphases added).

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B. In Construing "Machine-Readable Storage Medium," the Board Did Not Account for the Specification as a Whole

The Board founded its rejection on its observation that "[t]he Specification is devoid of any definition of 'machine-readable storage medium' that excludes a signal propagation medium or transitory medium." J.A. 13. The Board's analysis thus consisted of scanning the specification for an explicit statement that a machine-readable storage medium excludes transitory signals and, finding none, rejecting the claim under § 101. The Board's rigid approach falls afoul of this Court's guidance on claim interpretation, and should be rejected as a matter of law. It is legally erroneous to construe a claim term by looking for the presence or absence of a specific disclaimer, while donning blinders to the remainder of the claim language and written description disclosure. As this Court has explained, a claim term must be construed in light of "the specification as a whole." *In re Am. Acad. of Sci. Tech Ctr.*, 367 F.3d 1359, 1367 (Fed. Cir. 2004).

In view of the specification of the '053 application as a whole, the broadest reasonable interpretation of "machine-readable storage medium" does not cover a transitory signal. Nowhere does the specification even remotely suggest that "machine-readable storage medium" includes a transitory signal. To the contrary, the entirety of the '053 application is directed to a non-transitory computer system with which doctors and patients interact, which stores treatment information over substantial periods of time for subsequent access by patients, and which consists of

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tangible, commercially available components. The specification discloses, for example, that the claimed invention is implemented using a "computer 205," which includes "a memory 206 and a processor (CPU) 207, a *mass storage device* 208, and a network interface card (NIC) 209." J.A. 41 (emphasis added). The specification further states that "Computer 205 is preferably a Compaq Presario . . . manufactured by the Compaq Corporation." J.A. 41; *see also id.* ("Fig 2 is a block diagram of the computers used in the system); J.A. 136 (Fig. 2). The storage device contains various software programs including "Internet Explorer" and "Microsoft Access," both of which "Microsoft Corporation of Redmond, Washington manufactures." J.A. 42. There is nothing transitory about the "storage device" in this commercially available personal computer, J.A. 41, and the Board's contrary interpretation of the specification is legally erroneous.¹¹

District courts have construed similar claim terms in ways that tie them to the computer technology of which they are a part, without referencing a transitory signal. *See, e.g., Convolve, Inc. v. Dell, Inc.*, No. 2:08-CV-244-CE, 2011 WL 31792, at *19 (E.D. Tex. Jan. 5, 2011) (holding that "the term 'computer-readable medium' was well understood to one of ordinary skill in the art [and] refers to those media, such as hard disk drives, memories, compact disks, and floppy disks, that are commonly used to store and retrieve binary data and instructions for computer processors"); *Netscape Commc'ns Corp. v. ValueClick, Inc.*, 684 F. Supp. 2d 678, 693 (E.D. Va. 2009) (holding that "'a storage device' is an appropriate claim construction for 'computer readable medium'").

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C. The Opinion Relied on by the Board Undermines Its Decision

The Board's rejection of claim 28 under § 101 is legally erroneous for yet another reason: The principal opinion relied on by the Board in support of its rejection, Ex parte Mewherter, No. 2012-007692, 2013 WL 4477509 (PTAB May 8, 2013), directly undermines the Board's rejection here. See J.A. 13; see also J.A. 568–87. While *Mewherter* held that "those of ordinary skill in the art would understand the claim term 'machine-readable storage medium' would include signals per se," that holding was expressly limited to patent applications "dated 2002 and thereafter." 2013 WL 4477509, at *3 n.5, *7. Mewherter came to precisely the opposite conclusion about earlier applications; it observed that, "[a]s opposed to the voluminous extrinsic evidence dated 2002 and thereafter, which is discussed in this decision, before 2002 there is little evidence that the ordinary and customary meaning of such 'storage medium' terms encompassed a signal." Id. (emphasis added). Indeed, in *Mewherter*, the Board confirmed that a claim directed to an "article comprising a storage medium" was patent-eligible under § 101 where the patent application "ha[d] an effective filing date of May 25, 2000." Id. at *6 (confirming the correctness of Ex parte Mehta, No. 2008-004853, 2009 WL 4004962, at *3 (BPAI Nov. 18, 2009), in which the Board held that a claim directed to "an 'article comprising a storage medium" recites patent-eligible subject matter under § 101). As the Board in Mewherter explained, later-dated

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extrinsic evidence illustrating the meaning of such storage-medium terms "is inapplicable" to patent applications filed before 2002. *Id.* The Board entirely ignored the critical date limitation of the *Mewherter* decision.

Here, *Mewherter*'s holding that "machine-readable storage medium" encompasses a transitory signal is, likewise, "inapplicable." *Id.* The Board did not dispute that the '053 application is entitled to its August 1999 effective filing date. And as of 1999, "there is little evidence that the ordinary and customary meaning of such 'storage medium' terms encompassed a signal." *Id.* at *3 n.5.

* * *

Accordingly, because both the claim language and the specification of the '053 application demonstrate that claim 28 is directed to patent-eligible subject matter, and because the principal opinion relied on by the Board directly undermines its decision, the Board's rejection under § 101 is legally erroneous and should be reversed.

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CONCLUSION

For the foregoing reasons, Dr. Karpf respectfully requests that this Court vacate the Board's decision and reverse the rejections of claims 26 through 37.

Respectfully submitted,

/s/ Andrew V. Trask

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UNITED STATES PATENT AND TRADEMARK OFFICE

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte RONALD STEVEN KARPF

Appeal 2011-007657 Application 11/074,053 Technology Center 2100

Before JEAN R. HOMERE, DEBRA K. STEPHENS, and KRISTEN L. DROESCH, *Administrative Patent Judges*.

STEPHENS, Administrative Patent Judge.

DECISION ON APPEAL

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STATEMENT OF THE CASE

Appellant appeals under 35 U.S.C. § 134(a) from a final rejection of claims 26-37. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM-IN-PART and enter a NEW GROUND OF REJECTION UNDER 37 C.F.R. § 41.50(b).

Introduction

According to Appellant, the invention relates to a computer system and method for providing patients with access to information needed to understand and follow post-visit medical care instructions arising from a medical practitioner visit (Spec. 1).

Exemplary Claim

Claim 26, reproduced below, is illustrative of the claimed subject matter:

- 26. An electronic compliance promoter for use in promoting patient compliance with treatment instructions comprising:
- a medical personnel client, wherein said medical personnel client inputs from medical personnel diagnosis and treatment information regarding a patient following a medical appointment with the patient;
- a treatment server computer, wherein said treatment server computer receives diagnosis and treatment information from said medical personnel client; and
- a treatment instructions database, wherein said treatment instructions database stores the diagnosis and treatment information received from said treatment server computer;

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wherein said treatment server computer, responsive to access of said treatment server computer by the patient, outputs to the patient over a network the diagnosis and treatment information corresponding to the patient.

REFERENCE

Soll US 7,593,952 B2 Sept. 22, 2009 (filed Apr. 9. 1999)

REJECTION

The Examiner made the following rejection:

Claims 26-37 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Soll (Ans. 3).

We have only considered those arguments Appellant actually raised in the Brief. Arguments Appellant could have made but chose not to make in the Brief have not been considered and are deemed to be waived. *See* 37 C.F.R. § 41.37(c)(1)(vii)(2011).

ISSUE 1

35 U.S.C. § 102(e): Claims 26 and 28-34

As to claim 26, Appellant asserts the invention is not anticipated by Soll because Soll discloses a system intended to make health care *providers* (e.g., doctors) more productive whereas the claimed invention is directed to an apparatus used to promote compliance by a *patient* with particular treatment instructions (App. Br. 6). Specifically, Appellant argues Soll's disclosed "compliance attitudes" does not satisfy the "patient compliance" limitations of claim 26 (App. Br. 7 (citing Soll, col. 27, ll. 1-61)). Appellant

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further contends Soll's disclosed module is for automatically interviewing the patient to obtain their subjective input after a doctor's visit in order to determine the effectiveness of the doctor in interacting with the patient (*id.* (citing Soll, col. 27, ll. 9-11)). Thus, Appellant argues, Soll's "compliance attitudes" does not measure the actual compliance by the patient (e.g., with treatment instructions, etc.) because it is an exit interview feature for the sole benefit of the doctor and is not contemplated for use by the patient (App. Br. 8).

In addition, Appellant contends Soll does not teach a "medical personnel client" for use by medical personnel in inputting "diagnosis and treatment information" (App. Br. 8). Specifically, Appellant argues Soll shows the use of a patient module, not a medical personnel module, for use by the patient in an automated interview process prior to any possible diagnosis or treatment information generated by a physician (App. Br. 8-9, (citing Soll, col. 4 and 12)).

Issue 1a: Has the Examiner erred in finding Soll's module for an automatic exit interview measuring patient "compliance attitudes" teaches an "electronic compliance promoter for use in promoting patient compliance with treatment instructions," as recited in claim 26?

Issue 1b: Has the Examiner erred in finding Soll's patient module teaches the "medical personnel client," as recited in claim 26?

ANALYSIS

Issue 1a:

We are not persuaded by Appellant's arguments. While features of an apparatus may be recited either structurally or functionally, claims directed

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to an apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Schreiber*, 128 F.3d 1473, 1477-78 (Fed. Cir. 1997) (citations omitted). Here, Appellant attempts to distinguish the claims directed to an apparatus, i.e., "an electronic compliance promoter" from the prior art solely in terms function, i.e., "for use in promoting patient compliance with treatment instructions." Thus, this argument will not defeat the Examiner's finding of anticipation of the claimed apparatus if the prior art anticipates the structural limitations of the claims.

Further, assuming arguendo, the preamble of claim 26 is not merely intended use and is to be given patentable weight, we find Soll teaches "patient compliance with treatment instructions," as set forth by the Examiner (Ans. 14). Appellant's argument ignores the disclosure immediately following Soll's discussion of "compliance attitudes" wherein Soll states patients may access the comprehensive patient management ("CPM") system in the interim between the exit interview and the patient's next visit to the doctor (see Soll, col. 27, ll. 57-67 to col. 28, l. 3). Soll specifically discloses after the exit interview, the patient is given a printed health summary, including follow-up instructions and personalized health education materials (see Soll, col. 27, ll. 13-17). Soll also discloses patients may access the CPM from home via the Internet for triage, screening, or health education sessions (see Soll, col. 27, 11. 59-60). Further, Soll teaches when the CPM analysis of new patient information reveals a condition in need of prompt attention, the patient is instructed to seek care at the end of their CPM session (see Soll, col. 27, ll. 61-63).

Accordingly, we find Soll teaches "an electronic compliance promoter for use in promoting patient compliance with treatment instructions"

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because, after the exit interview, the patient is given a problem list with follow-up instructions (i.e., "treatment information") wherein the patient may subsequently access the CPM from home for screening and reveal a condition in need of prompt attention that causes the CPM to instruct the patient to seek care at the end of the session (i.e., "patient compliance"). Thus, the Examiner did not err in finding that Soll's disclosure of "compliance attitudes" teaches "patient compliance with treatment instructions."

Issue 1b:

We are not persuaded by Appellant's arguments. A claim containing a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (BPAI 1987) (citations omitted). Here, "medical personnel client" is merely a client intended to be employed by medical personnel, i.e., the phrase "medical personnel" is a non-functional descriptive label. Thus, any client capable of use by medical personnel reads on the claim limitation "medical personnel client."

Assuming *arguendo*, the phrase "medical personnel" in the "medical personnel client" claim limitation is not merely non-functional descriptive label and is to be given patentable weight, we agree with the Examiner's findings that Soll teaches doctors input patient information to be stored in a database (Ans. 15 (citing Soll, col. 26, l. 17 – col. 27, l. 3)). Soll teaches after the patient examination, problems are defined and management

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options, which are drawn from defined treatment guidelines, are selected by the physician (*see* Soll, col. 26, ll. 30-45). Thus, the Examiner did not err in finding Soll discloses the claimed "medical personnel client" because Soll teaches after the patient examination, the patient problems are defined (i.e., diagnosed) and the physician (i.e., medical personnel) enters treatment options for the diagnosis by selecting from a displayed list of predefined treatment guidelines.

Accordingly, we are not persuaded the Examiner erred in rejecting independent claims 26 and 28 and dependent claims 29-34, not separately argued, for anticipation by Soll.

ISSUE 2

35 U.S.C. § 102(e): Claim 27

Appellant contends claim 27 is not anticipated by Soll because a "treatment server computer" outputs to the patient information in a number of different formats such as: "in the form of a list of links to Web sites" and "a list of alerts in the form of patient symptoms that would require immediate medical attention" is absent from Soll (App. Br. 10).

Issue 2: Has the Examiner erred in finding Soll's disclosure of a reference on local resources such as a website provided at the exit interview teaches the treatment server outputting to the patient information "diagnosis information for the patient in the form of a list of links to Web sites that have the relevant diagnosis information," as recited in claim 27?

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ANALYSIS

We are not persuaded by Appellant's arguments. Claim 27 claims at least one of "diagnosis information for the patient in the form of a list of links to Web sites" and "a list of alerts in the form of patient symptoms that would require immediate medical attention." Thus, we need not determine whether Soll discloses the claimed "list of alerts" because a finding of the claimed "diagnosis information" is sufficient to meet the limitation.

The Examiner finds Soll discloses the claimed "diagnosis information." We agree with the Examiner's findings and adopt them as our own (Ans. 4 (citing Soll, col. 27, ll. 4-67)). Thus, the Examiner did not err in finding Soll's reference on local resources such as a website reads on the claimed "diagnosis information for the patient in the form of a list of links to Web sites that have the relevant diagnosis information" (*id.*).

Accordingly, we are not persuaded the Examiner erred in rejecting claim 27 for anticipation by Soll.

ISSUE 3

35 U.S.C. § 102(e): Claim 35

Appellant contends claim 35 is not anticipated by Soll. Specifically, Appellant argues that "rate" is never measured in any way for any aspect of the patient interaction in Soll (Reply Br. 10).

Issue 3: Has the Examiner erred in finding that Soll's discloses (1) the exit interview software monitors the rate of questions and answers; (2) patient access to the CPM via the Internet uses the same software as the exit interview; (3) therefore, Soll discloses "measuring a rate at which the patient reviews treatment information" as recited in claim 35?

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ANALYSIS

We are persuaded by Appellant's arguments. The Examiner finds the software used for the exit interview monitors the rate of the answers given by the patient (Ans. 21). The Examiner reasons the same software used at the exit interview is used by the patient to access treatment information via the internet and therefore, like the alleged rate monitoring by the exit interview software, the rate at which the patient accesses treatment information is similarly measured (*Id.*).

We find Soll teaches individualized feedback by the patient in response to a series of questions posed at the exit interview (*see* col. 27, ll. 19-55). Soll does not, however, disclose monitoring the rate at which the patient responds to these questions (*see* col. 27, l. 56 - col. 28, l.3). Further, we do not find Soll teaches the software used to facilitate the exit interview is the same software used by the patient to access treatment information via the Internet (*id.*). Thus, the Examiner erred in finding Soll discloses "measuring a rate at which the patient reviews treatment information" because rate is never measured in any way for any aspect of the patient interaction in Soll.

Accordingly, we are persuaded the Examiner erred in rejecting claim 35 for anticipation by Soll.

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ISSUE 4

35 U.S.C. § 102(e): Claims 36 and 37

Appellant contends claims 36 and 37 are not anticipated by Soll. Specifically, Appellant argues the cited passage merely relates to patient screening for common disorders and has nothing to do with patient compliance or the reminder function trigger by monitoring compliance, as required by claim 36 (App. Br. 12). Appellant maintains the Examiner effectively combines references from two totally different modules (patient home access and the revisit modules) to argue the combination has the single functionality claimed (Reply Br. 10).

Issue 4: Has the Examiner erred in finding: (1) Soll's patient home access module teaches the step of "issuing a reminder to the patient based on the compliance of the patient monitored" and (2) Soll's disclosure of instructing the patient to seek care at the end of their CPM session teaches "contacting the patient using at least one of: e-mail, mail, phone, beeper, and cable TV" as recited in claims 36 and 37?

ANALYSIS

We are not persuaded by Appellant's arguments. The Examiner finds Soll's disclosure of instructing the patient to seek care at the end of a CPM session that reveals a condition in need of prompt attention anticipates the claimed "reminder" and "contacting the patient using at least one of: e-mail, mail, phone, beeper, and cable TV" (Ans. 21-22 (citing Soll, col. 27, l. 56 - col. 28, l. 3, col. 28, ll. 44-67)).

We agree with the Examiner because the patient accesses the CPM in the interim between the exit interview and the next visit for triage, screening, Case: 14-1773 Document: 16 Page: 72 Filed: 01/09/2015

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or health education sessions (*see* Soll, col. 27, ll. 56-61). Upon the patient providing new information that reveals a new condition, the patient is instructed to seek care (*see* Soll, col. 27, ll. 62-64). The patient is instructed to seek care at the end of the CPM session, which is disclosed as occurring via the Internet (*see* Soll, col. 27, l. 59). Thus, we find the patient is instructed to seek care via information transferred electronically (i.e., e-mail) because the instruction occurs at the end of the CPM session, which is conducted via the Internet. As a result, we find Soll describes electronic mail because information is conveyed electronically.

In addition, we find the patient is instructed (i.e., reminded) to seek care following monitoring of patient compliance because the instruction to seek care is issued at the end of the CPM session wherein the patient has accessed the system for screening and health education sessions. Therefore, the Examiner did not err in finding Soll's patient compliance module anticipates "issuing a reminder to the patient based on the compliance of the patient monitored" and "contacting the patient using at least one of: e-mail, mail, phone, beeper, and cable TV."

Accordingly, we are not persuaded the Examiner erred in rejecting claims 36 and 37 for anticipation by Soll.

NEW GROUNDS OF REJECTION

Using our authority under 37 C.F.R. § 41.50(b), we reject claim 28 under 35 U.S.C. § 101 as being directed to non-statutory subject matter and reject claim 35 under 35 U.S.C. § 103(a) as being unpatentable over Soll.

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35 U.S.C. § 101: Claim 28

Claim 28 recites "[t]he article of manufacture comprising a machine-readable storage medium having stored therein indicia of a plurality of machine-executable control program steps. The Specification is devoid of any definition of "machine-readable storage medium" that excludes a signal propagation medium or transitory medium. Thus, interpreting "machine-readable storage medium" broadly, but reasonably, in light of the Specification, we determine the recited "machine-readable storage medium" encompasses transitory propagating signals (*see Ex parte Mewherter*, 107 USPQ2d 1857 (PTAB 2013) (precedential)).

Signals are unpatentable under § 101. *In re Nuijten*, 500 F.3d 1346, 1355 (Fed. Cir. 2007). According to U.S. Patent & Trademark Office (USPTO) guidelines:

A claim that covers both statutory and non-statutory embodiments . . . embraces subject matter that is not eligible for patent protection and therefore is directed to non-statutory subject matter. Such claims . . . should be rejected under 35 U.S.C. 101, for at least this reason.

For example, machine readable media can encompass non-statutory transitory forms of signal transmission, such as, a propagating electrical or electromagnetic signal *per se*. See *In re Nuijten*, 500 F.3d 1346, 84 USPQ2d 1495 (Fed. Cir. 2007).

Manual of Patent Examining Procedures ("MPEP") § 2106(I) (8th ed., 2001, Rev. 2012).

The USPTO also provides the following guidance:

The broadest reasonable interpretation of a claim drawn to a computer readable medium . . . typically covers forms of non-transitory tangible media and transitory propagating signals per se in view of the ordinary and customary meaning of computer

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readable media. . . . When the broadest reasonable interpretation of a claim covers a signal per se, the claim must be rejected under 35 U.S.C. § 101 as covering non-statutory subject matter.

David J. Kappos, Subject Matter Eligibility of Computer Readable Media, 1351 Off. Gaz. Pat. Office 212 (Feb. 23, 2010).

Therefore, we conclude claim 28 is not directed toward statutory subject matter under 35 U.S.C. § 101.

We have made the rejection regarding independent claim 28 under 37 C.F.R. § 41.50(b). However, we have not reviewed the remaining claims 29-37 to the extent necessary to determine whether these claims are directed to non-statutory subject matter. We leave it to the Examiner to determine the appropriateness of any further rejections based on these or other references. Our decision not to enter a new ground of rejection for all claims should not be considered as an indication regarding the appropriateness of further rejection or allowance of the non-rejected claims.

35 U.S.C. § 103(a): Claim 35

We find Soll anticipates base claim 28. Soll does not specifically disclose measuring the rate at which the patient reviews treatment information (*see* Soll col. 27, ll. 60-61). However, upon review of Soll's teachings, we conclude incorporating this feature would have been obvious to an ordinarily skilled artisan at the time of the invention in light of Soll. Specifically, we determine Soll describes a system that tracks when a patient returns to the CPM (*see e.g.* col. 8, ll. 39-44). Therefore, we determine Soll's system would inherently time stamp the patient's access of the CPM system because such systems necessarily record the time at which the system

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has been accessed by a user or at least suggest tracking the time a user accesses information, we determine an ordinarily skilled artisan would find Soll suggests such a feature. Thus, we conclude it would have been obvious to one of ordinary skill in the art (e.g., a network engineer) to include in the system of Soll, recording the number of times the patient has accessed the CPM over a given time period, i.e., measure the rate the patient has reviewed the health information sessions, to provide a doctor information to assess the weight the system should give to the user's information or how often the patient is seeking advice. In other words, the doctor may be given information that helps the doctor assess if at the rate at which the patient has accessed the system, for example, whether more weight is given to the patient information because the information is likely to be more accurate; whether the patient may be closely following instructions; or whether the patient continues to assess the information because the patient is confused by the instructions.

DECISION

The Examiner's rejection of claims 26 and 28-34 under 35 U.S.C. § 102(e) as being anticipated by Soll is affirmed.

The Examiner's rejection of claim 27 under 35 U.S.C. § 102(e) as being anticipated by Soll is affirmed.

The Examiner's rejection of claim 35 under 35 U.S.C. § 102(e) as being anticipated by Soll is reversed.

The Examiner's rejection of claims 36 and 37 under 35 U.S.C. § 102(e) as being anticipated by Soll is affirmed.

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We have entered new grounds of rejection against claim 28 under 35 U.S.C. § 101 and claim 35 under 35 U.S.C. § 103(a).

37 C.F.R. § 41.50(b)

This decision contains new grounds of rejection pursuant to 37 C.F.R. § 41.50(b). 37 C.F.R. § 41.50(b) provides "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review."

37 C.F.R. § 41.50(b) also provides the Appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new grounds of rejection to avoid termination of the appeal as to the rejected claims:

- (1) Reopen prosecution. Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the proceeding will be remanded to the examiner
- (2) *Request rehearing*. Request the proceeding be reheard under § 41.52 by the Board upon the same record

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv) (2011).

<u>AFFIRMED-IN-PART</u> 37 C.F.R. § 41.50(b)

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UNITED STATES PATENT AND TRADEMARK OFFICE

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte RONALD STEVEN KARPF

Appeal 2011-007657 Application 11/074,053 Technology Center 2100

Before JEAN R. HOMERE, DEBRA K. STEPHENS, and KRISTEN L. DROESCH, *Administrative Patent Judges*.

STEPHENS, Administrative Patent Judge.

DECISION ON REQUEST FOR REHEARING

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Appellant filed a Request for Rehearing under 37 C.F.R. § 41.52(a)(1) (hereinafter "Req. for Reh'g") for reconsideration of our Decision mailed December 12, 2013 (hereinafter "Decision").

Our Decision affirmed the Examiner's rejection of claims 26-34, 36, and 37 under 35 U.S.C. § 102(e) as being anticipated by Soll; reversed the Examiner's rejection of claim 35 under 35 U.S.C. § 102(e) as being anticipated by Soll; and entered new grounds of rejection against claim 28 under 35 U.S.C. § 101 and claim 35 under 35 U.S.C. § 103(a).

We have reconsidered our Decision, in light of Appellant's arguments in the Request for Rehearing, and we find no errors therein. We decline to change our prior Decision for the reasons discussed *infra*.

Appellant requests reconsideration of the following issues believed to have been misapprehended or overlooked by the Board.

ISSUE 1

We found in our Decision claim 26 was anticipated by Soll (Decision 14).

Appellant asserts the Board overlooked Appellant's arguments with respect to claim 26 and requests a new consideration of the arguments (Req. for Reh'g 2-3, 9-10). Claim 26 recites, in-part: "wherein said treatment server computer, responsive to access of said treatment server computer by the patient, outputs to the patient over a network the diagnosis and treatment information corresponding to the patient." In the Appeal Brief, Appellant asserted nothing in Soll describes a treatment server computer that outputs to the patient over a network the diagnosis and treatment information

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corresponding to the patient, as claimed (App. Br. 9). We are not persuaded Soll does not anticipate claim 26 for the reasons given in the Decision and as further explained below.

We found Soll describes patients may access the comprehensive patient management ("CPM") system in the interim between the exit interview and the patient's next visit to the doctor, from home via the Internet for triage, screening, or health education sessions (*see* Decision 5 (citing Soll, col. 27, l. 57–col. 28, l. 3); *see also* Ans. 9). Soll further describes the system is used to help physicians to a correct diagnosis of the complaint and seeks to educate the patient about his/her medical problems (diagnosis and treatment information) (Abstract).

As the Examiner noted, the CPM includes a patient module, physician module, and a server/database (Ans. 8, 16). The patient module and physician module are linked to the server/database—the treatment computer (*id.*). Therefore, we find Soll teaches a treatment server computer (server/database 30, FIG. 1) outputs diagnosis and treatment information over a network to a patient (patient carrel 10, FIG 1, or patient's home computer) in response to access by the patient, as claimed.

Accordingly, we are not persuaded Soll does not disclose "wherein said treatment server computer, responsive to access of said treatment server computer by the patient, outputs to the patient over a network the diagnosis and treatment information corresponding to the patient," as claimed.

As further support, although not relied upon in affirming the Examiner, we note Soll describes during the exit interview, the patient utilizes a patient carrel (10, FIG. 1) to access a server/database (30), which in response to the patient's access, provides diagnosis and treatment

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information (*see* Soll, step 1450 of FIG. 12, where patient is provided with a health summary, instructions, and educational material; *see also* FIG. 3, which shows CPM system server/database 180 providing the patient with such diagnosis and treatment information).

ISSUE 2

We found in our Decision claim 28 was anticipated by Soll (Decision 14).

Appellant asserts the Board overlooked Appellant's arguments with respect to the steps (b) and (c) limitations of claim 28 and requests (1) a new treatment of the argument and (2) a reconsideration of the new ground of rejection (Req. for Reh'g 3-4). Specifically, Appellant argues we have affirmed the Examiner's rejection of claim 28 for the same reasons provided for claim 26 and we performed no separate analysis of claim 28, which recites limitations substantially different from those in claim 26 (*id.*).

We have considered Appellant's request for a rehearing, however, we are not persuaded Appellant's arguments for claim 28 were overlooked, or Soll does not anticipate claim 28.

Claim 28 recites, in-part: "(b) determining access of the treatment information by a patient; and (c) monitoring compliance of the patient based on access of the treatment information." Appellant has argued Soll does not disclose these steps (App. Br. 10-11; Reply Br. 8-9), whereas the Examiner has maintained Soll does disclose these steps (Ans. 17-20).

In the Decision, we found Soll promotes patient compliance with treatment instructions by permitting the patient to access a CPM from a home computer where he or she can access information pertaining to triage, Case: 14-1773 Document: 16 Page: 82 Filed: 01/09/2015

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screening, and health education sessions (*see* Decision 5-6). Based on the patient accessing the CPM from home for screening, the CPM may instruct the patient to seek care at the end of the session (i.e., "patient compliance") (*see id.*). The patient's physician receives a notification of the patient's updated status as a means to monitor the compliance (*see* Soll, col. 27, 11. 22-24, 64-67).

Accordingly, Soll is considered to disclose the steps of "(b) determining access of the treatment information by a patient; and (c) monitoring compliance of the patient based on access of the treatment information," as claimed.

ISSUE 3

With respect to claim 28, Appellant further asserts the Board overlooked Appellant's arguments with respect to the "entering treatment information" limitation of claim 28 and requests a reconsideration of the argument (Req. for Reh'g 4-5). Specifically, Appellant argues we have improperly affirmed the Examiner's rejection of claim 28 for the reasons provided for claim 26, although claim 28 recites limitations substantially different from those in claim 26 (*id.*). Appellant contends the Examiner's citation to Soll (Ans. 5, citing col. 27, Il. 4-18) is directed to a patient "Exit Interview". *Id.* Appellant further argues entering of treatment information must be performed by a physician, not a patient. Req. Reh'g 5.

We decline to grant the request for a rehearing on this issue. Initially we note Appellant did not present these same arguments in the Appeal Brief. Instead, Appellant generally asserts "the passages in Soll . . . relied upon in

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the Office Action (at 6-7 and 10-12) never describe any attempt to enter the claimed 'treatment information' whatsoever. App Br. 11. Thus, the Board is not required to address these new arguments that could have been presented in the principal Brief. Nevertheless, analysis of this limitation was covered in the discussion of claim 26, which claims "input[ting] . . . treatment information" (see Decision 6-7). To emphasize, we found Soll discloses doctors input patient information to be stored in a database (Decision 6; Ans. 15; see also Soll, Abstract). We further found Soll teaches after the patient examination, the patient problems are defined (i.e., diagnosed) and the physician enters treatment options for the diagnosis by selecting from a displayed list of predefined treatment guidelines (Decision 7(citing Soll col. 26, Il. 30-45); Ans. 15). Moreover, we note claim 28 does not specify who/what inputs treatment information—a term not explicitly defined in the Specification.

Accordingly, we are not persuaded Soll does not disclose "entering treatment information" recited in claim 28.

ISSUE 4

We introduced a new ground of rejection for claim 28 under 35 U.S.C. § 101 (Decision 15). Appellant requests reconsideration (Req. for Reh'g 4), but has not provided sufficient substantive reasons for such reconsideration. Thus, we decline to reconsider the new ground of rejection under 35 U.S.C. § 101 for claim 28.

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ISSUE 5

We found in our Decision claim 27 was anticipated by Soll (Decision 14).

Appellant asserts the Board misapprehended claim 27 (Req. for Reh'g 5). Specifically, Appellant argues we have affirmed the Examiner's rejection of claim 27 without the Examiner or the Board providing any analysis of the arguments. We are unpersuaded by this assertion inasmuch as both the Examiner (Ans. 16-17) and the Board (Decision 7-8) have already addressed Appellant's arguments in respect to claim 27. Accordingly, we decline to grant the request for a rehearing on this issue.

ISSUE 6

We found in our Decision claim 36 was anticipated by Soll (Decision 14).

Appellant asserts the Board misapprehended claim 36, and specifically, Soll does not anticipate claims 36 (Req. for Reh'g 5-8). We are unpersuaded by this assertion inasmuch as the Decision already addressed Appellant's arguments in respect to claim 36 (*see* Decision 10-11). Claim 36 recites "issuing a reminder to the patient based on the compliance of the patient monitored in said monitoring step." The Examiner relied on Soll, column 27, line 56 to column 28, line 3 and column 28, lines 44-67 (Ans. 21). We found Soll's CPM issuing instructions to a patient (alert) to seek care following monitoring of patient compliance corresponded to the claimed "reminder" (*see* Decision 11; *see also* col. 27, ll. 61-64). Accordingly, we decline to grant the request for a rehearing on this issue.

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ISSUE 7

We found in our Decision claim 37 was anticipated by Soll (Decision 14).

Appellant asserts the Board misapprehended claim 37, and specifically, Soll does not anticipate claim 37 (Req. for Reh'g 8-9). We are unpersuaded by this assertion inasmuch as the Decision already addressed Appellant's arguments in respect to claim 37 (see Decision 10-11). Claim 37 recites, *inter alia*, "said issuing step (d) is performed by contacting the patient using . . . e-mail." We found Soll's CPM issuing instructions to a patient to seek care following monitoring of patient compliance corresponded to the claimed "e-mail" (see Decision 11). That is, instructions transmitted to a patient electronically, such as via the Internet, are broadly interpreted as electronic mail (*id.*). Accordingly, we decline to grant the request for a rehearing on this issue.

CONCLUSION

We have considered the arguments raised by Appellant in the Request for Rehearing, but find none of these arguments persuasive that our original Decision was in error. It is our view Appellant has not identified any points the Board has misapprehended or overlooked. Based on the record before us, we are still of the view the invention set forth in claims 26-34, 36, and 37 is anticipated by the applied prior art, the invention set forth in claim 35 is obvious over the applied prior, and the invention set forth in claim 28 is directed to non-statutory subject matter. We have reconsidered our Decision but decline to grant the relief requested.

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Our decision remains <u>AFFIRMED-IN-PART</u> with new grounds of rejection pursuant to <u>37 C.F.R § 41.50(b)</u>.

This Decision on Appellant's Request for Rehearing is deemed to incorporate our earlier Decision (mailed December 12, 2013) by reference. *See* 37 C.F.R. § 41.52(a)(1).

DECISION

We have granted Appellant's request to the extent we have reconsidered our Decision of December 12, 2013, but we deny the request with respect to making any changes therein.

REHEARING DENIED

msc

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CERTIFICATE OF SERVICE

I, Andrew V. Trask, counsel for Appellant and a member of the Bar of this Court, certify that on January 9, 2015, a copy of the foregoing Brief for Appellant Ronald S. Karpf was filed electronically and served via operation of the Court's CM/ECF system upon counsel of record:

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Attorneys for the Director of the U.S. Patent and Trademark Office

January 9, 2015

/s/ Andrew V. Trask

ANDREW V. TRASK

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CERTIFICATE OF COMPLIANCE

I, Andrew V. Trask, counsel for Appellant and a member of the Bar of this Court, certify, pursuant to Federal Rule of Appellate Procedure 32(a)(7)(B), that the attached Brief for Appellant Ronald S. Karpf is proportionally spaced, has a typeface of 14 points or more, and contains 12,045 words.

January 9, 2015

/s/ Andrew V. Trask

ANDREW V. TRASK